Notice of Allowability	Application No. 09/937,643	Applicant(s) PHILLIPS ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the communication filed 5/7/04*.

2. ☒ The allowed claim(s) is/are *26-50,66-69,71,73,75 and 77*.

3. ☒ The drawings filed on *27 September 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date attached
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413) Paper No./Mail Date *attached* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DAVE T. NGUYEN
PRIMARY EXAMINER

Jon Eric Angell

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sima Kulkarni on 6/4/04.

The application has been amended as follows:

On page 5, the beginning of line 4 of the specification, the phrase "FIG. 6." Has been changed to "FIG. 6A and B." to more accurately reflect drawing figure 6.

Note: claims 1-25 have been cancelled.

Claim 26 has been replaced with:

-- 26. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells. --

Claim 36 has been replaced with:

-- 36. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells,

wherein the inhibition of proliferation of said prostate cancer cells is caused by induction of apoptosis in the prostate cancer cells, induction of cytokine synthesis in the prostate cancer cells, or induction of cytokine synthesis by immune cells in the prostate. –

Claim 40 has been replaced with:

-- 40. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on mycobacterial cell wall (BCC); and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells.

Claim 47 has been replaced with:

-- 47. The method of claim 40, wherein the inhibition of proliferation of said prostate cancer cells is caused by induction of apoptosis in the prostate cancer cells, induction of cytokine synthesis in the prostate cancer cells, or induction of cytokine synthesis by immune cells in the prostate. –

Claim 48 has been replaced with:

-- 48. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on mycobacterial cell wall (BCC); and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells, wherein the inhibition of proliferation of said prostate cancer cells is caused by induction of apoptosis

in the prostate cancer cells, induction of cytokine synthesis in the prostate cancer cells, or induction of cytokine synthesis by immune cells in the prostate. –

Note: Claims 51-65 have been cancelled.

Claim 66 has been replaced with:

-- 66. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) a predetermined amount of mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells, wherein the amount of B-DNA administered is from about 0.00001 to about 200mg/kg per dose. –

Claim 69 has been replaced with:

--69. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) *M. phlei* DNA (M-DNA) obtained from a disrupted *M. phlei* mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells.

Claim 70 has been cancelled.

Claim 71 has been replaced with:

-- 71. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) *M. phlei* DNA (M-DNA) obtained from a disrupted *M. phlei* mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells, wherein the inhibition of proliferation of said prostate cancer cells is caused by induction of apoptosis in the prostate cancer cells, induction of cytokine synthesis in the prostate cancer cells, or induction of cytokine synthesis by immune cells in the prostate. –

Claim 72 has been cancelled.

Claim 73 has been replaced with:

-- 73. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) *M. phlei* DNA (M-DNA) obtained from a disrupted *M. phlei* mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the *M. phlei* DNA is preserved and complexed on *M. phlei* cell wall (MCC); and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells. –

Claim 74. has been cancelled.

Claim 75 has been replaced with:

-- 75. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) *M. phlei* DNA (M-DNA) obtained from a disrupted *M. phlei* mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells, wherein the inhibition of proliferation of said prostate cancer cells is caused by induction of apoptosis in the prostate cancer cells, induction of cytokine synthesis in the prostate cancer cells, or induction of cytokine synthesis by immune cells in the prostate. –

Claim 76 has been cancelled.

Claim 77 has been replaced with:

-- 77. A method of inhibiting proliferation of prostate cancer cells in an animal or human having prostate cancer, comprising administering at the prostate cancer cells a composition comprising:

(a) a predetermined amount of *M. phlei* DNA (M-DNA) obtained from a disrupted *M. phlei* mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

in an amount effective to inhibit proliferation of said prostate cancer cells, wherein the amount of M-DNA administered is from about 0.00001 to about 200mg/kg per dose. –

Claim 78 has been cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell. Ph.D.
Art Unit 1635

DAVE T. NGUYEN
PRIMARY EXAMINER